UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,343	09/18/2003	Megan Anne Diehl	A01341 US-3	7043
	7590 03/19/200 [AAS COMPANY	EXAMINER		
PATENT DEPARTMENT			QAZI, SABIHA NAIM	
100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106-2399			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			03/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/665,343	DIEHL ET AL.		
Office Action Summary	Examiner	Art Unit		
	Sabiha Qazi	1612		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).		
Status				
Responsive to communication(s) filed on 29 Ja This action is FINAL . 2b)☑ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1,3 and 7-15 is/are pending in the appending of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1, 3 and 7-15 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	wn from consideration. r election requirement.			
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplished any accomplished any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) ☑ Notice of References Cited (PTO-892)	4)	(PTO-413)		
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite		

Application/Control Number: 10/665,343 Page 2

Art Unit: 1612

Non Final Office Action

Claims 1, 3 and 7-15 are pending. No claim is allowed at this time. Amendments are entered. This RCE has been filed after the Board decision on 11/24/2008, where Examiner was affirmed.

Summary of this Office Action March 15, 2009

- 1. Information Disclosure Statement
- 2. Copending Applications
- 3. Specification
- 4. 35 USC § 103(a) Rejection
- 5. Response to Remarks and Declaration
- 6. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Application/Control Number: 10/665,343 Page 4

Art Unit: 1612

Claim Rejections - 35 USC § 103

1. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 7-15 rejected under 35 U.S.C. 103(a) as being unpatentable over ANTONI-ZIMMERMANN et al. 1 and Applicants disclosure. See the entire document especially abstract of the invention, lines 3-67 in column 2; lines 1-67 in column 3; lines 1-67 in column 4; examples and claims of ANTONI-ZIMMERMANN and Entire specification of the present invention.

ANTONI-ZIMMERMANN teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances which embraces Applicant's claimed invention. The biocide composition that is improved in its components interact synergistically and therefore can be used in lower concentrations when used simultaneously, compared to the concentrations necessary in the case of the individual components. Thus, humans and the environment are exposed to less pollution and the costs of controlling harmful microorganisms are reduced. This object is achieved by the invention by means of a biocide composition having at least two active biocidal substances, one of which is 2-methylisothiazolin-3-one. The reference further teaches that biocide

¹ US Patent 6,361788

composition of the invention has the advantage that it can replace active substances used until now in practice, but suffering from disadvantages with respect to health and the environment, e.g., 5-chloro-2-methylisothiazolin-3-one (see lines 3-41 in column 2 and lines 33-38 in column 4). Moreover, the biocide composition of the invention can be produced with water as a favorable medium, if necessary. The addition of emulsifiers, organic solvents, and/or stabilizers is thus not necessary. Moreover the invention makes it possible to match the composition to specific goals by adding further active substances, for example, in the sense of an increased biocidal activity, improved long-term protection of the substances infected by microorganisms, improved compatibility with the substances to be protected, or improved toxicological or ecotoxicological behavior (lines 49-54, column 4).

The reference further teaches biocide composition of the invention contains 2-methylisothiazolin-3-one and 1, 2-benzisothiazolin-3-one, normally in a weight ratio of (50-1): (1-50), preferably in a weight ratio of (15-1): (1-8), in particular in a weight ratio of (4-1) (1-4). A weight ratio of 1:1 is particularly preferred. In the biocide composition the 2-methylisothiazolin-3-one and the 1,2-benzisothiazolin-3-one are present in a total concentration of preferably 0.5 to 50% by wt, in particular 1 to 20% by wt, particularly preferred 2.5 to 10% by wt, in each case relative to the total biocide composition.

The reference further teaches that the biocide composition of the invention can be used in very different fields. It is suitable, for example, for use in paints, plasters, lignosulfonates, chalk suspensions, adhesives, photochemicals, casein-containing products, starch-containing products, bituminous emulsions, surfactant solutions, motor fuels, cleaning agents, cosmetic products, water circulating systems, polymer dispersions, and cooling lubricants, against attack by, for example, bacteria, filamentous fungi, yeasts, and algae. The reference teaches a list of some active biocidal compounds, which includes presently claimed biocidal compound such as benzyl alcohol, (claim 8), sorbic acid, benzoic acid, phenoxy ethanol, (claim 1) and many others. See column 3 and 4.

Specification discloses that all the compounds are well known biocides, see the entire document especially pages 1 and 2 where it teaches that the compounds are known.

Instant claims differ from the reference in claiming synergistic combination in specific ratios of the components.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions for inhibiting synergistically the growth of microorganisms by using the teachings of the prior art to combine 2-methylisothiazoline and one or two active biocidal component.

The ratio of the two components to find the synergism is a routine expectation for the one who is skilled in the art because the biocide composition of the reference teaches combination of at least two active biocidal substances, one of which is 2methylisothiazolin-3-one. The composition can contain one or more other active biocidal substances selected according to the field of application. Specific examples are listed in columns 3 and 4. Present invention does mention only one biocide 2-methyl-3-isothiazolone, however, the term "comprising" allows other componenets to be added. Other biocides listed in column 3 and 4 include the compounds which are presently claimed. The combination with zinc pyrithione and climbazole is not mentioned specifically in the prior art however, Applicants specification discloses that all the biocides are commercially available. All the compounds are individually known as biocides. The reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances Therefore, using 2-methyl-3 isothiazolone for synergism would have been obvious to one skilled in the art at the time invention was made.

The motivation to prepare synergistic biocidal compositions and method of inhibiting microorganisms as presently claimed has been provided by the prior art.

The discovery of an optimum value of a result effective variable in a

known process is ordinarily within the skill of the art. Synergism is one factor to be considered in the ultimate determination of obviousness of the composition.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); < Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) where it was held that "Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak, 455 F.2d

1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra".

In absence of any criticality and/or unexpected results presently claimed invention would have been *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Data in the Specification

The data presented in the specification was considered The data presented covers the combination of 2-isothiazole and benzoic acid (Table 1), citric acid (Table 2), sorbic acid (Table 3), 1,2-dibromo-2,4-dicyclobutane (Table 4), 1,3-dimethylol-5,5-dimethylhydantion (Table 5), henoxyethanol (Table 6), zinc pyrithione (Table 7), climbazole (Table 8), and benzyl alcohol (Table 9). The data presented is for certain organisms. Further, the synergistic combinations have been

taught by the prior art. The synergism as claimed would have been expected for reasons cited above.

Response to Remark and Declaration

Declaration filed on 01.23.2009 by Eileen F. Warwick has been considered. Examiner respectfully disagree that claimed subject matter is not obvious over the disclosure of the references. The question is that whether or not the present invention would have been obvious at the time the invention was filed. Examiner believes that one skilled in the art would have been able to prepare the combinations as claimed because the any skilled in the art would expect that the when two active compounds which are known to have synergic results can combine various ratios, some of them may be synergistic some of them may not be synergistic.. It is an experimental observation and out of testing various combinations at different concentrations one can collect the data in the laboratory. Examiner has shown that the synergistic combination of 2-methylisothiazolin-3one and various other active biocidal substances is improved in its components interact synergistically and therefore can be used in lower concentrations when used simultaneously, compared to the concentrations necessary in the case of the

individual components. Thus, humans and the environment are exposed to less pollution and the costs of controlling harmful microorganisms are reduced. This object is achieved by the prior art by means of a biocide composition having at least two active biocidal substances, one of which is 2-methylisothiazolin-3-one. The reference further teaches that biocide composition of the invention has the advantage that it can replace active substances used until now in practice, but suffering from disadvantages with respect to health and the environment, e.g., 5-chloro-2-methylisothiazolin-3-one.

Moreover, Applicant argue that the reference does not disclose combinations comprising 2-methyI-3"isothiazolone and zinc pyrithione, climbazole or citric acid, as recited in claims 7, 8 and 11, respectively. The combination with zinc pyrithione and climbazole is not mentioned specifically in the prior art however, Applicants specification discloses that all the biocides are commercially available. All the compounds are individually known as biocides. The reference teaches the synergistic combination of 2-methylisothiazoline and various other active biocidal substances Therefore, using 2-methyl-3 isothiazolone for synergism would have been obvious to one skilled in the art at the time invention was made. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not

exclude additional, unrecited elements or method steps. See, e.g., >Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

In summary Examiner concludes that claims and specification does not provide any new concept or patentable invention for the reasons cited above.

See KSR Supreme Court of United States Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350) where it states that (1) "However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic

control to the support bracket of pedal assembly". (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws".

See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) where it has been held that "Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides."

"There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result".

"Assuming arguendo that the differences in values presented are statistically

significant, there is no evidence that they represent a true, practical advantage. In re Freeman, <u>474 F.2d 1318</u>, <u>177 USPQ 139</u> (CCPA 1973); In re Klosak , <u>455 F.2d 1077</u>, <u>173 USPQ 14</u> (CCPA 1972); In re D'Ancicco, <u>439 F.2d 1244</u>, <u>169 USPQ 303</u> (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, <u>800 F.2d 1091</u>, <u>231 USPQ 375</u> (Fed.Cir. 1986); In re Longi , <u>759 F.2d 887</u>, <u>225 USPQ 645</u> (Fed.Cir. 1985); In re Freeman, supra".

See KSR Supreme Court of United States Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350) where it states that (1) "However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly". (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws".

In summary Examiner concludes that claims and specification does not provide any new concept or invention for the reasons cited above. To emphasize this point Examiner would like to refer to Applicants to Genetech, 108 F.3d at 1366 and Brenner 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)" which states

that "a patent is not a hunting license. It is not a reward for research, but a compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable."

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/665,343 Page 18

Art Unit: 1612

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR

only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to

the automated information system, call 800-786-9199 (IN USA OR CANADA) or

571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1612